# Clinical Priorities Advisory Group Summary Report

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| **Agenda item** | |
| **Date of Meeting** | 11.05.26-13.05.2026 |
| **Title of the Proposition** | Stereotactic ablative body radiotherapy for primary kidney cancer |
| **Unique Reference Number** | 2332 |
| **Programme of Care** | Cancer |
| **Clinical Reference Group** | Radiotherapy |
| **Service/treatment status** | delegated |

## Action requested

Support the adoption of the policy proposition

Recommend its relative prioritisation.

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## Summary of the proposition:

Renal cancer, which is also called renal cell carcinoma (RCC) or primary kidney cancer, is a malignancy that originates in the lining of the proximal convoluted tubule of the kidney. It is the most frequent malignant disorder of the kidney in adults, but is uncommon, accounting

for 4% of all new cancer cases in the UK (CRUK, 2023) with an incidence in 2020 of approximately 10,500 cases (CancerData, 2023).

The policy proposition has been developed following completion of an independent review of papers related to the treatment of adult patients with stage I (T1a (≤4cm) and T1b (>4cm but ≤7cm), N0, M0 cancers) RCC who are medically unfit for surgery using SABR. Patients medically unfit for surgery include patients medically unfit for a general anaesthetic and patients with inoperable tumours due to technical reasons, e.g. position of tumour.

Additional evidence for this topic was requested by Clinical Panel members to help determine whether SABR has a clinical benefit to patients with T1b kidney cancer who are unable to have surgery for their disease (first-line therapy), compared to no treatment noting that active surveillance is not recommended in patients with T1b, N0, M0 renal cancers,

Three research papers were identified by the Policy Working Group (PWG) that provide evidence on the natural history of localised kidney cancer. The most significant study presented was a retrospective review by Grant et al in 2019. SABR (any dose) was associated with a 44% statistically significant decreased risk of death compared to observation, and higher doses of SABR were associated with a 66% decreased risk of death compared to observation. Lower doses of SABR were associated with a 10% decreased risk of death compared to observation, which was not statistically significant. Based on this research study, Panel members were informed that a higher dose may be more effective.

Panel members agreed that the additional evidence was more compelling than that previously presented and noting the improvements reported across the research studies, supported the proposition. Panel members also agreed that it is important to ensure that clinical and safety outcomes prioritised for the previous evidence review are captured in an appropriate registry for the medically inoperable 1b population in the policy proposition.

To note that following assurances, a NICE guideline Kidney cancer: diagnosis and management was published on 19th March 2026. The NHS England policy proposition proposes considering SABR for people with solid renal masses larger than 4 cm who cannot have surgery; this is consistent with NICE recommendations. However, NICE also recommends the use of SABR in patients who have renal masses between 2-4cm or Bosniack cysts greater than 2cm, which is not included in this policy proposition.

## Clinical Panel recommendation:

The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy.

## Assurances

| The committee is asked to receive the following assurance: | |
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| 1. | The Deputy Director of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of developmental and governance steps. |

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| 2. | The Deputy Director of Cancer Programme confirms the proposition is supported by the following documentation (please tick the box where applicable) | |
| | Draft Clinical Commissioning policy proposition | ☒ |
| | Evidence Review | ☒ |
| | Public Health Evidence Report | ☒ |
| | Evidence to Decision Making (EtD) Summary | ☒ |
| | Equalities and Heath Inequalities Assessment (EHIA) | ☒ |
| | Prior Approval Form | ☒ |
| | Engagement Report | ☒ |
| | 13Q Assessment and Patient & Public Voice Assurance | ☒ |
| | Clinical Panel Report | ☒ |
| | Policy Working Group membership | ☒ |
| | Other – Three Study Paper Summary | ☐ |
| 3. | The Deputy Director of Finance (Specialised Commissioning) confirms that the Impact Assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal. | |
| 4. | The Director of Clinical Commissioning (Specialised Commissioning) confirms that the Service and Operational Impact Assessments have been completed. | |
| 5. | The Deputy Director of Quality and Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined (where applicable). | |

# Evidence Review Summary

### In people with medically inoperable localised primary kidney cancer, what is the clinical effectiveness and safety of SABR treatment +/- supportive care compared with current standard care alone?

| Outcome | Evidence statement |
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| **Clinical Effectiveness** | |
| **Critical outcomes** | |
| **Local control** | Local control is important to patients because it reflects how effective the treatment is at preventing the cancer from growing or spreading. Local failure carries detrimental symptoms for the patient alongside the psychological burden of the recurrence of cancer. |

| Outcome | Evidence statement |
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| **Certainty of evidence:**<br><br>Very low | Two prospective and three retrospective case series provided evidence relating to local control measured at different time points up to four years. None of the studies included a comparator group.<br><br>**At 6 months follow-up**<br>• One prospective case series (Zarkar et al 2023) (n=15) (median follow-up 17 months, range 5 to 32 months) reported partial response for 3 patients and stable disease for 12 patients based on RECIST criteria[1]; a median reduction in tumour size of 16.67% (IQR 2.7 to 28.0) and a rate of local control of 94.4% (95% CI 66.6% to 99.2%). **(VERY LOW)**<br><br>**At 12 months follow-up**<br>• The same prospective case series (Zarkar et al 2023) (n=15) (median follow-up 17 months, range 5 to 32 months) reported partial response for 5 patients and stable disease for 9 patients based on RECIST criteria; a median reduction in tumour size of 26.5% (IQR 7.9 to 34.5) and a rate of local control of 94.4% (95% CI 66.6% to 99.2%). **(VERY LOW)**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a cumulative incidence of local failure of 5.85%. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported an objective tumour size reduction in 61% of RCCs. **(VERY LOW)**<br><br>**At median follow-up of 16 months**<br>• One retrospective case series (Sun et al 2016) (n=41 tumours) (mean follow-up 561 days, median 489 days) reported progressive disease for 1 tumour (2.4%), stable disease for 31 (75.6%), partial response for 8 (19.5%) and complete response 1 tumour (2.4%). This study also reported <5mm growth[2] for 38 tumours (92.7%) and *statistically significant reductions* in mean tumour growth rate (average of 3 linear dimensions) (before SABR 0.68 cm/year, after SABR -0.37 cm/year, p<0.0001 for each dimension) and in mean tumour volume growth rate (before SABR 21.21 $cm^3$/year, after SABR -5.35 $cm^3$/year, p=0.002). It reported narratively that there was a *"Statistically significant decrease of … the size of renal tumours"* after SABR (p-value not reported) and that no subsequent growth that met criteria for response to treatment subsequently did not meet criteria. **(VERY LOW)**<br><br>**At 2 years follow-up or two years median follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a cumulative incidence of local failure of 7.77%. **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported local control rates, based on RECIST criteria, of 98.0% for patients with a solitary kidney. One patient had local disease recurrence. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported partial response for 4 patients and stable disease for 28 patients at last follow-up based on RECIST criteria. **(VERY LOW)**<br><br>**At 4 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a cumulative incidence of local failure of 7.77%. **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported local control rates, based on RECIST |

[1] RECIST is a set of published rules that define when tumours in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment.
[2] This figure included tumours that decreased in size or did not change in size

| Outcome | Evidence statement |
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| | criteria, of 98.0% for patients with a solitary kidney. One patient had local disease recurrence. **(VERY LOW)**<br><br>**Five case series that included patients with medically inoperable, localised RCC provided very low certainty evidence relating to local control rates. Rates of failure of local control reported were under 10% up to four years after treatment with SABR. 61% of patients had an objective reduction in tumour size at one year in one study. *Statistically significant* reductions in mean tumour growth rates and tumour size were reported in another study. However, without a comparator group in any of the studies, it is not clear how this compares with local control rates for people who receive other treatments or supportive care instead of SABR.** |
| **Overall survival**<br><br>**Certainty of evidence:**<br><br>Very low | Overall survival is important to patients because it reflects how long people live after treatment, although it does not take the cause of death into account, or provide information about their health and wellbeing during that time.<br><br>Two prospective and two retrospective case series provided evidence relating to overall survival measured at different time points up to 4 years. None of the studies included a comparator group.<br><br>**At 6 months follow-up**<br>• One prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported an overall survival rate of 94.7% (95% CI 68.1% to 99.2%). **(VERY LOW)**<br><br>**At 12 months follow-up**<br>• The same prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported an overall survival rate of 78.3% (95% CI 51.9% to 91.3%). Of the 7 deaths, 6 were not related to SABR or RCC (cardiac arrest (1), sepsis (1), heart failure (1), left ventricular failure (1), pneumonia (2)) **(VERY LOW)**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) and a prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) both reported an overall survival rate of 100%. **(VERY LOW)**<br><br>**At 2 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported an overall survival rate of 100%. **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported an overall survival rate of 81.5% for patients with a solitary kidney. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported an overall survival rate of 92% (95% CI 81% to 100%). **(VERY LOW)**<br><br>**At 4 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported an overall survival rate of 91.6%. **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported an overall survival rate of 73.6% for patients with a solitary kidney. **(VERY LOW)**<br><br>**Four case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to overall survival rates. Two of the studies reported overall survival rates of over 90%, with one study reporting results up to four years after SABR (overall survival rate 91.6%). A third study reported an overall survival rate of 78.3% at one year (six of the seven deaths in** |

| Outcome | Evidence statement |
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| | **this study were not related to SABR or RCC), and a fourth study reported overall survival of 73.6% at four years. The relatively small size of the studies meant that confidence intervals for survival rates, where reported, were relatively wide (for example 81% to 100% at two years). In addition, without a comparator group in any of the studies, it is not clear how these overall survival rates compare with overall survival rates for people who receive other treatments or supportive care instead of SABR.** |
| **Progression free survival**<br><br>**Certainty of evidence:**<br><br>Very low | Progression free survival is important to patients because it represents the time for which their disease is not progressing. Stable disease might represent longer survival and that patients experience less symptoms from the disease itself. It can be determined sooner than overall survival outcome measure and is therefore a useful outcome for studies with shorter follow-up periods.<br><br>Two prospective and two retrospective case series provided evidence relating to progression free survival measured at different time points up to four years. None of the studies included a comparator group.<br><br>**At 12 months follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported progression free survival of 91.4% (cumulative incidence of local progression 5.85%; cumulative incidence of distant metastasis 4.24%, 1 lung, 1 spine, 1 adrenal). **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported progression free survival of 97% (95% CI 91% to 100%) (freedom from distant progression 97%, 95% CI 91% to 100%; freedom from local progression 100%). **(VERY LOW)**<br><br>**At median follow-up of 17 months**<br>• One prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported that 1 patient had local progression and 2 had distant progression. **(VERY LOW)**<br><br>**At 2 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported progression free survival of 89.7% (cumulative incidence of local progression 7.77%; cumulative incidence of distant metastasis 4.24%, 1 lung, 1 spine, 1 adrenal). **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported a progression free survival rate of 77.5% for patients with a solitary kidney. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported progression free survival of 89% (95% CI 78% to 100%) (freedom from distant progression 89%, 95% CI 78% to 100%; freedom from local progression 100%). **(VERY LOW)**<br><br>**At 4 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported progression free survival of 89.7% (cumulative incidence of local progression 7.77%; cumulative incidence of distant metastasis 4.24%, 1 lung, 1 spine, 1 adrenal). **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported a progression free survival rate of 68.3% for patients with a solitary kidney. **(VERY LOW)**<br><br>**Four case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to progression free survival rates, with two studies reporting results up to four years after SABR treatment (progression free survival rate 89.7% and 68.3% respectively). Rates of close to 90% were reported at two years after SABR in two studies while the third study reported a progression free survival rate of 77.5% at 2 years. The relatively small** |

| Outcome | Evidence statement |
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| | **size of the studies meant that confidence intervals for survival rates, where reported, were relatively wide (for example 78% to 100% at two years). In addition, without a comparator group in any of the studies, it is not clear how these progression free survival rates compare with progression free survival rates for people who receive other treatments or supportive care instead of SABR.** |
| **Important outcomes** | |
| **Cancer specific survival**<br><br>**Certainty of evidence:**<br>Very low | Cancer specific survival is important to patients because it reflects how long people live after treatment and excludes death due to causes unrelated to the cancer, although it does not provide information about their health and wellbeing during that time.<br><br>One prospective case series and one retrospective case series provided evidence relating to cancer specific survival. The study did not include a comparator group.<br><br>**At median follow-up of 17 months**<br>• One prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported 1 death related to cancer. **(VERY LOW)**<br><br>**At 2 years follow-up**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported a cancer specific survival rate of 98.2% for patients with a solitary kidney. **(VERY LOW)**<br><br>**At 4 years follow-up**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported a cancer specific survival rate of 98.2% for patients with a solitary kidney. **(VERY LOW)**<br><br>**Two case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to cancer specific survival rates, reporting one death related to cancer over a median follow-up period of 17 months in one study and a cancer specific survival rate of 98.2% up to 4 years in the second study. Without a comparator group in the study, it is not clear how this compares with cancer specific survival rates for people who receive other treatments or supportive care instead of SABR.** |
| **Time to further intervention**<br><br>**Certainty of evidence:**<br>Not applicable | Time to further intervention is important to patients because it is linked to disease progression, which carries detrimental symptoms for the patient alongside the psychological burden of the recurrence of cancer. Further intervention carries the risks of treatment related complications and effects on quality of life.<br><br>**No evidence was identified for this outcome.** |
| **Health related quality of life (QoL)** | Health related QoL is important to patients because it provides a holistic evaluation and indication of the patient's general health and their perceived well-being and their ability to participate in activities of daily living. This outcome is both a key indicator of the effectiveness of treatment and provides an insight into the patient's perception of the effectiveness of treatment.<br><br>One prospective case series provided evidence relating to health related QoL measured at different time points up to 6 months after SABR. The study did not include a comparator group. For the EQ-5D-3L scores, higher values indicate improvement. For the EORTC-QLQ-C15-PAL scores, higher values indicate, depending on the measure, higher quality of life, higher functioning or higher symptom burden. For the |

| Outcome | Evidence statement |
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| **Certainty of evidence:**<br><br>Very low | overall converted FACT FKSI-19 score, higher scores indicate fewer symptoms. For each of the three QoL tools used, the MCID in each direction (improvement or worsening) was reported and was used in making the assessment regarding "stable", "better" or "worse" QoL. For EORTC, the MCID used was 10 points in either direction, for the EQ-5D-3L overall health state score it was 0.08 and for the FACT total score it was 5 points.<br><br>**At 1 week follow-up**<br>• One prospective case series (Swaminath et al 2021) (n=32) reported changes in the EQ-5D-3L scores from baseline:<br>  • Visual analogue scale (n=16): -0.938<br>  • Health utility score (n=20): 0.050 (85.0% stable or better vs 15.0% worse). **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported changes in the EORTC-QLQ-C15-PAL scores from baseline together with the % that were stable or better vs the % that were worse: (p-value only reported for Global QoL score)<br>  • Global QoL score (n=20): -8.345 (45.0% vs 55.0%) (p=0.046)<br>  • Physical functioning (n=20): -0.665 (80.0% vs 20.0%)<br>  • Emotional functioning (n=20): -2.920 (65.0% vs 35.0%)<br>  • Fatigue (n=20): 7.225 (60.0% vs 40.0%)<br>  • Nausea and vomiting (n=20): 5.000 (90.0% vs 10.0%)<br>  • Dyspnoea (n=19): 0.005 (95.0% vs 5.0%)<br>  • Pain (n=20): 1.667 (70.0% vs 30.0%)<br>  • Insomnia (n=20): -5.000 (85.0% vs 15.0%)<br>  • Appetite (n=20): 5.000 (80.0% vs 20.0%)<br>  • Constipation (n=19): 1.754 (90.0% vs 10.0%). **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported the change in the overall converted FACT FKSI-19 score from baseline (n=20): 0.430 (85.0% stable or better vs 15.0% worse) **(VERY LOW)**<br><br>**At 1 month follow-up**<br>• One prospective case series (Swaminath et al 2021) (n=32) reported changes in the EQ-5D-3L scores from baseline:<br>  • Visual analogue scale (n=22): 1.500<br>  • Health utility score (n=23): 0.022 (79.2% stable or better vs 20.8% worse) **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported changes in the EORTC-QLQ-C15-PAL scores from baseline together with the % that were stable or better vs the % that were worse:<br>  • Global QoL score (n=24): -3.479 (70.8% vs 29.2%)<br>  • Physical functioning (n=24): 1.388 (83.3% vs 16.7%)<br>  • Emotional functioning (n=24): 2.087 (75.0% vs 25.0%)<br>  • Fatigue (n=24): 4.642 (62.5% vs 37.5%)<br>  • Nausea and vomiting (n=24): 0.000 (87.5% vs 12.5%)<br>  • Dyspnoea (n=24): -0.008 (83.3% vs 16.7%)<br>  • Pain (n=24): 0.694 (66.7% vs 37.3%)<br>  • Insomnia (n=24): -2.778 (79.2% vs 20.8%)<br>  • Appetite (n=24): 1.383 (70.8% vs 29.2%)<br>  • Constipation (n=23): 4.348 (79.2% vs 20.8%) **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported the change in the overall converted FACT FKSI-19 score from baseline (n=24): 0.908 (70.8% stable or better vs 29.2% worse) **(VERY LOW)** |

| Outcome | Evidence statement |
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| | **At 3 months follow-up**<br>• One prospective case series (Swaminath et al 2021) (n=32) reported changes in the EQ-5D-3L scores from baseline:<br>  • Visual analogue scale (n=16): 4.125<br>  • Health utility score (n=17): -0.020 (76.5% stable or better vs 23.5% worse) **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported changes in the EORTC-QLQ-C15-PAL scores from baseline together with the % that were stable or better vs the % that were worse:<br>  • Global QoL score (n=17): -0.982 (70.6% vs 29.4%)<br>  • Physical functioning (n=16): -5.000 (68.3% vs 31.3%)<br>  • Emotional functioning (n=17): 1.471 (76.5% vs 23.5%)<br>  • Fatigue (n=17): 1.318 (70.6% vs 29.4%)<br>  • Nausea and vomiting (n=17): -6.859 (100% vs 0%)<br>  • Dyspnoea (n=17): 1.969 (88.2% vs 11.8%)<br>  • Pain (n=17): -3.922 (76.5% vs 23.5%)<br>  • Insomnia (n=17): 3.922 (64.7% vs 25.3%)<br>  • Appetite (n=17): -9.812 (94.1% vs 5.9%)<br>  • Constipation (n=16): 4.167 (94.1% vs 5.9%)<br>  **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported the change in the overall converted FACT FKSI-19 score from baseline (n=17): -2.188 (64.7% stable or better vs 35.3% worse) **(VERY LOW)**<br><br>**At 6 months follow-up**<br>• A prospective case series (Swaminath et al 2021) (n=32) reported changes in the EQ-5D-3L scores from baseline:<br>  • Visual analogue scale (n=15): 1.667 (p=0.398, appears to be p-value for trend[3])<br>  • Health utility score (n=16): 0.038 (81.3% stable or better vs 18.8% worse) (p=0.493, appears to be p-value for trend)<br>  **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported changes in the EORTC-QLQ-C15-PAL scores from baseline, together with the % that were stable or better vs the % that were worse, and p-values which appear to relate to trend over the 6 month period:<br>  • Global QoL score (n=16): -2.083 (68.8% vs 31.3%) (p=0.390)<br>  • Physical functioning (n=16): -7.494 (56.3% vs 43.8%) (p=0.225)<br>  • Emotional functioning (n=16): -3.119 (75.0% vs 25.0%) (p=0.848)<br>  • Fatigue (n=16): 2.781 (68.8% vs 31.3%) (p=0.586)<br>  • Nausea and vomiting (n=16): -3.125 (100.0% vs 0.0%) (p=0.401)<br>  • Dyspnoea (n=16): 14.581 (68.8% vs 31.3%) (p=0.126) (p=0.048 at 6 months compared to baseline)<br>  • Pain (n=16): -6.250 (81.3% vs 18.8%) (p=0.979)<br>  • Insomnia (n=16): 4.167 (68.8% vs 31.3%) (p=0.543)<br>  • Appetite (n=16): -2.088 (93.8% vs 6.3%) (p=0.279)<br>  • Constipation (n=16): 4.167 (81.3% vs 18.8%) (p=0.838)<br>  **(VERY LOW)**<br><br>• The same prospective case series (Swaminath et al 2021) (n=32) reported the change in the overall converted FACT FKSI-19 score from baseline (n=16): - |

[3] P-values were reported below graphs showing baseline, 1 week and 1, 3 and 6 month mean scores and standard errors. It is not clear if they are p-values for trend. The narrative reports that "Means of converted scores (+/-standard deviations) were also compared at each time point to the baseline using paired t-tests." However only 2 of these p-values were reported (these have been included here).

| Outcome | Evidence statement |
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| | 0.181 (68.8% stable or better vs 31.3% worse) (p=0.330, presumed to be p-value for trend) **(VERY LOW)**<br><br>**One prospective case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to health related QoL outcomes over a six month follow-up period using three different tools that include a variety of QoL-related metrics. No statistically significant change in any QoL metric was reported over the 6 month period. Two of the many comparisons of individual time points to baseline for individual metrics resulted in p-values just below 0.05, but given the number of comparisons made, they do not reliably indicate statistical significance. The large amount of missing data at each time point further reduces the certainty of the results. In addition, without a comparator group included in the study, it is not clear how the results reported in this case series compare with health related QoL for people who receive other treatments or supportive care instead of SABR.** |
| **Organ specific disease response**<br><br>**Certainty of evidence:**<br><br>Very low | Organ specific disease response is important to patients because reduction in renal function may lead to requirement for renal replacement therapies such as dialysis which have a significant impact on mortality, morbidity and quality of life.<br><br>Two prospective case series and one retrospective case series provided evidence relating to organ specific disease response or kidney function measured at different time points up to four years. None of the studies included a comparator group.<br><br>**At 6 months follow-up**<br>• One prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported a mean change in eGFR from baseline of -5.4 ml/min (95% CI -10.3 to -0.6). **(VERY LOW)**<br><br>**At 12 months follow-up**<br>• One prospective case series (Zarkar et al 2023) (n=19) (median follow-up 17 months, range 5 to 32 months) reported a mean change in eGFR from baseline to 12 months of -8.7 ml/min (95% CI -15.3 to -2.1) and from 6 months to 12 months of -5.1 ml/min (95% CI -9.0 to -1.1). **(VERY LOW)**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a median change in eGFR from baseline of -7.0ml/min (IQR -14.5 to -1.0). This study also reported that 18.8% of patients had an improved eGFR compared to baseline and that the proportion of renal function from the ipsilateral (SABR-treated) kidney changed from 47% (IQR 44 to 53) at baseline to 39% (IQR 37 to 48) at 12 months. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported a mean change in eGFR from baseline of -11ml/min (95% CI -6 to -17), p<0.001. **(VERY LOW)**<br><br>**At 20 to 28 months follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a median change in eGFR from baseline to 2 years of -11.5ml/min (IQR -19.5 to -4.0) and reported that over the whole study follow-up period (median 27.8 months) there was a *statistically significant* decrease in eGFR (p<0.0001) and the proportion of patients with stage 3+ chronic kidney disease increased over time (p-value not reported). The number of patients on dialysis also increased from 2 (2.7%) to an additional 4 (5.4%) patients. This study also reported that 15% of patients had an improved eGFR at 2 years compared to baseline and that the proportion of renal function from the ipsilateral (SABR-treated) kidney changed from 47% (IQR 44 to 53) at baseline to 36% (IQR 36 to 42) at 2 years, with the proportion of renal function from the ipsilateral kidney decreasing significantly over the period of the study (p<0.0001). **(VERY LOW)**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported a mean change in eGFR from baseline to the latest time point measured (median 20.4 months) for patients with a solitary |

| Outcome | Evidence statement |
|---|---|
| | kidney of -5.8 ml/min (SD ± 10.8). The median change was -3.3 ml/min (range -35.1 to 18.7). The mean eGFR before SABR was 64.6 ml/min (SD ± 21.7, median 67.6, range 13.0 to 126.3). The mean eGFR after SABR was 59.2 ml/min (SD ± 23.9, median 62.1, range 8.0 to 100.4). After SABR, the percentage of patients with normal renal function was 10.8%, mild CKD 44.6%, mild to moderate CKD 20.0%, moderate to severe CKD 10.8% and severe CKD 13.9%.[4] This study also reported that at last measurement, 14 patients (21.5%) had an eGFR that was reduced compared to baseline by ≥15 ml/min, 17 patients (26.2%) had an increase in eGFR compared to baseline and no patients were on dialysis. **(VERY LOW)**<br>• One prospective case series (Siva et al 2017) (n=33) (median follow-up 24 months, minimum 12 months) reported a mean change in eGFR from baseline to 2 years of -11ml/min (95% CI -3 to -19) for a subset of n=9 patients. **(VERY LOW)**<br><br>**At 4 years follow-up**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a median change in eGFR from baseline of -14.0ml/min (IQR -28.0 to -10.0). This study also reported that 0% of patients had an improved eGFR compared to baseline and that the proportion of renal function from the ipsilateral (SABR-treated) kidney had changed from 47% (IQR 44 to 53) at baseline to 32.5% (IQR 29 to 39.5) at 4 years. **(VERY LOW)**<br><br>**Four case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to changes in renal function, with one study reporting results up to four years after SABR treatment. The studies reported a *statistically significant* reduction in eGFR of -5.4ml/min at six months to a larger reduction (-14ml/min) at four years, although confidence intervals were relatively wide. One study also reported improvements in eGFR in 18.8% of patients at one year and 15% at two years reducing to 0% at four years and another study reported an increase in eGFR in 26.2% of patients with a solitary kidney at a median of 20.4 months. One study reported an increase in the number of patients on dialysis (5.4% increase) and the number with stage 3 chronic kidney disease, as well as a reduction in the proportion of renal function from the SABR-treated kidney over the course of the study (median follow-up 28 months). A second study (in patients with a solitary kidney) reported no patients on dialysis at a median of 20.4 months after SABR. Without a comparator group in any of the studies, it is not clear how these changes compare with changes in renal function in people who receive other treatments or supportive care instead of SABR.** |
| **Safety** | |
| **Safety outcomes**<br><br>**Certainty of evidence:**<br><br>Very low | Safety is important to patients as it reflects the risks involved in treatment. This allows a risk benefit assessment to be undertaken.<br><br>Two prospective case series provided evidence relating to safety, reporting on adverse events up to a median of 24 months follow-up. Neither of the studies included a comparator group.<br><br>**Acute adverse events ≤90 days after SABR (median follow-up 24 months, minimum 12 months)**<br>• One prospective case series (Siva et al 2017) (n=33) reported acute adverse events by Grade as follows: |

[4] Correa et al (2019) defined the stages of CKD as follows: normal renal function: eGFR≥90; mild CKD: eGFR 60 to <90; mild to moderate CKD: eGFR 45 to <60; moderate to severe CKD: eGFR 30 to <45; severe CKD: eGFR <30. The percentage of patients in each CKD category at baseline was 5.0%, 62.5%, 15.0%, 8.8% and 8.8% respectively.

| Outcome | Evidence statement |
|---|---|
| | • Grade 1: 11 patients (33%) had at least one event (chest wall pain 5, dermatitis 2, diarrhoea 3, fatigue 11, gastritis 1, nausea 5, right flank pain 1)<br>• Grade 2: 7 patients (21%) had at least one event (dyspnoea 1, fatigue 6, gastritis 1, nausea 2)<br>• Grade 3: none<br>**(VERY LOW)**<br><br>**Late adverse events >90 days after SABR (median follow-up 24 months, minimum 12 months)**<br>• One prospective case series (Siva et al 2017) (n=33) reported late adverse events by Grade as follows:<br>• Grade 1: 17 patients (52%) had at least one event (chest wall pain 12, diarrhoea 1, dyspnoea 2, fatigue 7, gastritis 1, haematuria 3, nausea 2, skin induration 1)<br>• Grade 2: 2 patients (6%) had at least one event (abdominal pain 1, haematuria 1)<br>• Grade 3: 1 patient (3%) had fatigue<br>**(VERY LOW)**<br><br>**Acute plus late adverse events after SABR (median follow-up 24 months, minimum 12 months)**<br>• One prospective case series (Siva et al 2017) (n=33) reported adverse events by Grade as follows:<br>• Grade 1: 19 patients (58%) had at least one event (chest wall pain 15, dermatitis 2, diarrhoea 3, dyspnoea 2, fatigue 14, gastritis 2, haematuria 3, nausea 5, right flank pain 1, skin induration 1)<br>• Grade 2: 7 patients (21%) had at least one event (abdominal pain 1, dyspnoea 1, fatigue 5, gastritis 1, haematuria 1, nausea 2)<br>• Grade 3: 1 patient (3%) had fatigue<br>**(VERY LOW)**<br><br>**Worst grade of each type of adverse event over each patient's follow-up period (median follow-up 17 months, range 5 to 32 months)**<br>• One prospective case series (Zarkar et al 2023) (n=19) reported patients' worst grade of adverse event by type of adverse event. They reported that the number (and %) of patients having a Grade 0, 1, 2, 3 and 4 adverse event as the worst grade of that type of adverse event for that patient was as follows:<br>Grade 0, 1, 2, 3, 4<br><br>• Fatigue: 4 (21.1%), 12 (63.3%, 3 (15.8), 0 and 0 patients<br>• Gastritis: 17 (89.5%), 1 (5.3%), 1 (5.3%), 0, 0 patients<br>• Anaemia: 17 (89.5%), 0, 1 (5.3%), 1 (5.3%), 0 patients<br>• Pain: 18 (97.4%), 1 (5.3%, 0, 0, 0 patients<br>• Nausea: 14 (73.7%), 1 (5.3%), 4 (21.1%), 0, 0 patients<br>• Vomiting: 17 (89.5%), 1 (5.3%), 1 (5.3%), 0, 0<br>• Colitis: 18 (94.7%), 0, 0, 1 (5.3%), 0 patients<br>• Diarrhoea: 17 (89.5%), 2 (10.5%), 0, 0, 0 patients<br>• Haematuria: 18 (94.7%), 0, 0, 1 (5.3%), 0 patients<br>• Haemorrhage: 18 (94.7%), 1 (5.3%), 0, 0, 0 patients<br>**(VERY LOW)**<br><br>**Two case series that included patients with medically inoperable localised RCC provided very low certainty evidence relating to adverse events following SABR. One study (n=33) reported that 58% of patients had at least one Grade 1 adverse event, 21% had at least one Grade 2 event and 3% had at least one Grade 3 event, with the Grade 3 event being fatigue in one patient more than 90 days after SABR. The second study (n=19) reported the worst Grade of each type of adverse event over each patient's follow-up period. Most types of adverse events listed were not reported at all by over 89% of patients, except for fatigue (63.3% of patients had Grade 1 fatigue and 15.8% had Grade 2 fatigue) and nausea (5.3% of** |

| Outcome | Evidence statement |
|---|---|
| | **patients had Grade 1 nausea and 21.1% had Grade 2 nausea). Grade 3 adverse events (anaemia, colitis and haematuria) were experienced by single patients. Without a comparator group in either of the studies, it is not clear how many of these events are experienced by people who receive other treatments or supportive care instead of SABR.** |

**Abbreviations**
CI: confidence interval; $cm^3$: cubic centimetres; CKD: chronic kidney disease; eGFR: estimated glomerular filtration rate; EORTC QLQ-C15-PAL: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 15 Palliative Care; EQ-5D-3L: European Quality of Life 5 Dimensions 3 Level; FACT FKSI: Functional Assessment of Cancer Therapy – Kidney Specific Index; IQR: Interquartile range; ml/min: MCID: minimal clinically important difference; millilitres per minute; mm: millimetres; QoL: quality of life; RCC: renal cell carcinoma; RECIST: Response Evaluation Criteria in Solid Tumours; SABR: stereotactic ablative body radiotherapy

## In people with medically inoperable localised primary kidney cancer, what is the cost-effectiveness of SABR treatment +/- supportive care compared with current standard care alone?

| Outcome | Evidence statement |
|---|---|
| Cost effectiveness | One study was identified that provided evidence for the cost effectiveness of SABR compared to RFA over a 5-year time horizon for people with inoperable early stage (confined to the kidney, node negative) RCC. It was based on using 5 fractions of SABR, with costs based on the Canadian public health care payer's perspective (1.5%/year discount rate) including costs of supplies, personnel and capital/machinery but not individual patient rehabilitation or medication costs. Outcomes were based on data obtained on review of literature, with varying rates used for sensitivity analyses.<br><br>**5-year time horizon:**<br>*SABR vs RFA*<br>• One analysis (Donovan et al 2022) reported that SABR was cost effective compared to RFA (ICER CAD -4,490 per QALY gained (95% CI not reported)). This was based on costs of SABR and RFA of CAD 16,097 and CAD 18,324 respectively and QALYs gained of 4.109 and 3.607 for SABR and RFA respectively. Sensitivity analysis suggested significant variability in the ICER with variations in rates of distant metastases having the greatest implications followed by utility values.[5] Varying other parameters resulted in smaller changes to the ICER.<br><br>**One recent cost effectiveness analysis compared treatment of patients with inoperable early stage RCC with SABR compared to treatment with RFA over a 5-year time horizon based on the Canadian health care payer's perspective (including costs of personnel, supplies and capital but not rehabilitation and medication costs). This study reported that SABR was cost effective compared to RFA (ICER of CAD -4,490 per QALY gained). Sensitivity analyses suggested that the rate of distant metastasis had the greatest impact on calculated ICERs followed by utility values. The Canadian perspective of this study and any recent changes in treatment of metastatic RCC may limit its generalisability to the current NHS in England.** |

[5] In health economics, a 'utility' is the measure of the preference or value that an individual or society gives a particular health state.

**Abbreviations**
CAD: Canadian dollar; CI: confidence interval; ICER: Incremental cost effectiveness ratio; QALY: Quality-adjusted life year; RCC: renal cell carcinoma; RFA: radiofrequency ablation; SABR: stereotactic ablative body radiotherapy

## From the evidence selected, are there any subgroups of patients that may benefit from SABR treatment +/- supportive care more than the wider population of interest?

| Outcome | Evidence statement |
|---|---|
| T1a vs T1b tumours[6] | From the studies selected for inclusion in this review, one retrospective case series reported subgroup results for treatment of T1a vs T1b inoperable RCCs with SABR for the critical outcomes of local control, overall survival and progression free survival. The study did not include a comparator group of patients that did not receive SABR.<br><br>**Critical Outcomes**<br>**Local control**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a univariate analysis of local control rates (based on RECIST criteria[7]) for T1b tumours (n=34) vs T1a tumours (n=32) and reported a HR of 1.1 (95% CI 0.08 to 14.0), p=0.97.<br><br>**Overall survival**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a univariate analysis of overall survival rates for T1b tumours (n=34) vs T1a tumours (n=32) and reported a HR of 0.51 (95% CI 0.007 to 35.5), p=0.76.<br><br>**Progression free survival**<br>• One retrospective case series (Glicksman et al 2023) (n=74) (median follow-up 27.8 months, IQR 17.6 to 41.7) reported a univariate analysis of progression free survival rates for T1b tumours (n=34) vs T1a tumours (n=32) and reported a HR of 2.5 (95% CI 0.30 to 20.6), p=0.40. A corresponding HR for distant metastasis rates was reported as HR 1.6 (95% CI 0.13 to 18.9), p=0.72.<br><br>**Important Outcomes**<br>**Organ specific disease response**<br>• One retrospective case series (Correa et al 2019) (n=81) (median follow-up 2.57 years, 95% CI 2.12 to 3.33) reported that tumour diameter ≥4.0cm was *statistically significantly* associated with an eGFR decrease of 15 ml/min or greater (OR 4.21 (95% CI 1.16 to 15.31), p=0.029, univariable logistic regression analysis).<br><br>**Cost effectiveness**<br>• One cost effectiveness analysis (Donovan et al 2023) reported the cost effectiveness of SABR compared to RFA over a 5-year time horizon for people with inoperable early stage RCC from the perspective of the Canadian public health care payer and included a comparison of ICERs for T1b vs T1a tumours. This suggested that SABR was considerably more cost effective compared to RFA for T1b tumours (ICER per QALY gained CAD -22,904) |

[6] The term T1a includes patients with tumours between 0 and 4cm in maximum diameter; the term T1b includes patients with tumours between 4 and 7cm in maximum diameter.
[7] RECIST is a set of published rules that define when tumours in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment.; follow-up every 3 to 6 months till 5 years.

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| | compared to T1a tumours (ICER per QALY gained CAD 2,207).[8] (T1b tumours: cost of SABR CAD 19,245, cost of RFA CAD 37,427, QALYs gained with SABR 4.067, QALYs gained with RFA 3.459 vs T1a tumours: cost of SABR CAD 14,993, cost of RFA CAD 13,940, QALYs gained with SABR 4.119, QALYs gained with RFA 3.641).<br><br>**One retrospective case series reported HRs for the critical outcomes of local control, overall survival and progression free survival for people with T1b vs T1a inoperable RCC who received treatment with SABR. No statistically significant differences were observed in these outcomes for T1b compared to T1a tumours. Another retrospective case study reported a statistically significant association between having a tumour of ≥4cm and having a 15ml/min or greater decrease in eGFR after SABR treatment. Without a comparator group included in these studies, it is not clear whether outcomes are significantly different for T1b vs T1a tumours in people who receive other treatments or supportive care instead of SABR.**<br><br>**One recent cost effectiveness analysis reported a substantially higher cost effectiveness of SABR for people with T1b tumours (ICER per QALY gained CAD -22,904) compared to T1a tumours (ICER per QALY gained CAD 2,207).** |
| T1a tumours suitable for ablative procedures vs not suitable for ablative procedures | **No evidence was identified pertaining to these subgroups from the studies selected for inclusion in this review.** |
| Solitary kidney vs 2 kidneys | **No evidence was identified pertaining to these subgroups from the studies selected for inclusion in this review.[9]** |
| Anticoagulant use vs no anticoagulant use | **No evidence was identified pertaining to these subgroups from the studies selected for inclusion in this review.** |
| **Abbreviations**<br>RCT: Randomised controlled trial; STAMPEDE: Systemic Therapy for Advanced or Metastatic Prostate Cancer: Evaluation of Drug Efficacy | |

## From the evidence selected, what dose, fractionation and duration of SABR were used?

| Outcome | Evidence statement |
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| **Dose, fractionation and duration of SABR** | One retrospective case series (Correa et al 2019) reported outcomes for patients with RCC in a solitary kidney who were treated with SABR (n=81). The mode of SABR treatment was not reported. The mean total dose used was 28.9Gy (SD ± 12.3), with a median dose of 25.0Gy (range 14.0 to 70.0). The mean number of treatment fractions provided was 1.9 (SD ± 2.5) (range 1 to 10). 13 patients (16.1%) received a single fraction. The mean fraction dose was 22.1Gy (SD ± 6.0), and the median dose was 25.0Gy (range 6.0 to 26.0). The mean biological equivalent dose was also reported: 86.8Gy (SD ± 14.4, median 87.5Gy, range 33.6 to 124.8). The timing of fractions and the duration of time required to deliver the SABR treatment were not reported. |

[8] These ICER results were reported in the abstract and narrative; Table 3 of the paper reported slightly different results: ICER per QALY gained of CAD -29,905 for T1b tumours and CAD 2,208 for T1a tumours.
[9] Although Correa et al 2019 compared outcomes for a group of patients with a solitary kidney and a group with two kidneys, there was no indication that patients in the group with two kidneys were medically inoperable. Hence the group with two kidneys and the comparison between the two groups were not within the scope of the PICO framework for this review.

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| | One retrospective case series (Glicksman et al 2023) (n=74) reported outcomes for patients with localised RCC who were deemed medically inoperable or unresectable or declined surgery who were treated with SABR (intensity modulated radiotherapy (2 patients, 2.7%) or volumetric modulated arc therapy (72 patients, 97.3%)) with either 30 to 45Gy in 5 fractions or 42Gy in 3 fractions, based on physician decision. Treatment was delivered on alternate days: 1 patient (1.4%) received 30Gy in 5 fractions; 22 patients (29.7%) received 35Gy in 5 fractions; 41 patients (55.4%) received 40Gy in 5 fractions; 6 patients (5.4%) received 45Gy in 5 fractions; 4 patients (8.1%) received 42Gy in 3 fractions.[10] The duration of time required to deliver the SABR treatment was not reported.<br><br>One prospective case series (Siva et al 2017) (n=37) reported outcomes for patients with small RCC who were medically inoperable, high risk for surgery or refused surgery who were treated with SABR using conventional c-arm linear accelerator. RCCs that were <5cm maximum dimension were treated with 26Gy in a single fraction (n=17). RCCs that were ≥5cm maximum dimension were treated with 42 Gy in 3 fractions on non-consecutive days (n=17). 33 of the 37 patients received all treatments (to 34 RCCs) (1 patient died prior to SABR; 1 patient completed 2 of 3 planned fractions because of social difficulties; 2 patients could not meet planned dose constraints). The duration of time required to deliver the SABR treatment was not reported.<br><br>One retrospective case series (Sun et al 2016) (n=40, 41 tumours) reported outcomes for patients with renal masses deemed to be poor candidates for surgery or minimally invasive tumour ablation who were treated with SABR using the CyberKnife system with the Synchrony system (Accuracy) to track movement. The mean SABR dose used was 38Gy (range 21 to 48) delivered in daily fractions. Initially 21 Gy was delivered in 3 fractions. Over the course of the study, this was gradually increased to 48 Gy delivered in 3 fractions (3 tumours were treated with 21Gy, 1 with 24Gy, 4 with 27Gy, 5 with 30Gy, 2 with 33Gy, 2 with 36Gy, 8 with 39Gy, 1 with 45Gy and 15 with 48Gy). The duration of time required to deliver the SABR treatment was not reported.<br><br>One prospective case series (Swaminathan et al 2021) (n=32) reported outcomes for patients with non-metastatic RCC who were medically inoperable, ineligible for other locally ablative treatments or refused surgery who were treated with SABR using a volumetric modulated arc therapy approach. Patients received either 35 to 45Gy in 5 fractions (35Gy: 16 patients, 50%; 40Gy: 11 patients, 34.4%; 45Gy: 1 patient, 3.1%) or 42Gy in 3 fractions (4 patients, 12.5%) delivered every second day. The dose was selected based on tumour size, location within the kidney, and proximity to upper abdominal organs at risk. The duration of time required to deliver the SABR treatment was not reported.<br><br>One prospective case series (Zarkar et al 2023) (n=19) reported outcomes for patients with T1 stage RCC who were non-surgical candidates and were treated with SABR using volumetric modulated arc therapy (n=11) or CyberKnife (n=8). Patients received either 26Gy in 1 fraction (n=8) or 42Gy in 3 fractions on alternate days (n=11). The duration of time required to deliver the SABR treatment was not reported.<br><br>One cost effectiveness study (Donovan et al 2022) based the cost effectiveness analysis on treatment with 5 fractions of SABR. The dose and duration of treatment were not reported.<br><br>**The six included case series delivered SABR treatment (volumetric arc therapy, intensity modulated therapy, CyberKnife) at doses varying from 21Gy to 70Gy in different numbers of fractions ranging from one to ten. Different regimens tended to be used within individual studies. Where reasons for this were reported it was either based on physician decision, tumour size, location within the kidney, proximity to upper abdominal organs at risk or changes in practice over the duration of the study. Where multiple fractions were used, one study reported these being daily and four studies reported that fractions were** |

[10] These figures were reported in Table 2 of the paper. However, 6/74 is in fact 8.1% and 4/74 is 5.4%.

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| | **delivered on alternate or non-consecutive days. None of the studies reported the duration of time required to deliver the SABR treatment.** |

**Abbreviations**

Gy Gray; RCC: renal cell carcinoma; SABR: stereotactic ablative body radiotherapy; T stage: tumour stage

# Patient Impact assessment

The Patient Impact form provides additional background information to Clinical Priorities Advisory Group (CPAG) on the impact of the medical condition for which the proposed treatment is indicated. The details below specifically reference the lived experience of patients and caregivers. This supporting information will help CPAG members contextualise the clinical evidence for a treatment or service. It does not change the methodology used to make decisions when considering in year service development policy propositions or policy propositions entered in to the prioritisation process.

**The condition has the following impacts on the patient's everyday life:**

- **mobility:** Patients have moderate problems in walking about
- **ability to provide self-care:** Patients have moderate problems in washing or dressing
- **undertaking usual activities:** Patients have moderate problems in doing their usual activities
- **experience of pain/discomfort:** Patients have moderate pain or discomfort
- **experience of anxiety/depression:** Patients are moderately anxious or depressed

**Further details of impact upon patients:**
People with untreated T1b (>4cm, ≤7cm), N0, M0 renal cancer may experience haematuria and pain which may limit mobility and exercise tolerance, resulting in patients being unable to fully participate in self-care and usual activities. This may significantly decrease quality of life. Progressive disease may cause worsening local and metastases-related symptoms (with no curative treatment for metastases). This may cause more difficulties participating in usual activities and require additional carer support.

Many people suffer with anxiety/depression as a result of their diagnosis which may significantly decrease quality of life and participation in usual activities. This may be exacerbated by a lack of treatment options.

**Further details of impact upon carers:**
Renal cancer may lead to moderate burden on carers, who may need to assist the patient with self-care and usual activities, with increasing burden as the patient's disease progresses. Anxiety/depression as a result of the patient's diagnosis may affect relationships between the patient and their family/carers.

## Considerations

| Equality and Health Inequalities Impact Assessment (EHIA) | |
|---|---|
| Summary of any potential impacts of the proposal | The EHIA has highlighted that primary kidney cancer is more common with increasing age, with 34% of patients being above 75 years at diagnosis. It is more common in men than in women. It is more common in the White ethnic group compared with in the Asian and Black ethnic groups. It is more common in deprived areas.<br><br>The implementation of the policy proposition is considered to have a positive impact for people with disabilities.<br>• Patients with T1b, N0, M0 RCC who are medically unfit for surgery, may be medically unfit for a variety of reasons and, for these same reasons, are also likely to be members of this protected characteristic group e.g. multimorbidity or frailty. They currently have no active treatment options, until they progress to a later stage, where treatment is more intensive, has more side effects and is unlikely to be curative.<br><br>• This policy proposition would bring their treatment options in line with patients with T1a, N0, M0, who are medically unfit for surgery who currently have a number of active and potentially curative treatment options, including NICE-approved invasive ablative procedures; cryotherapy (NICE, 2011) or radio-frequency ablation (NICE, 2010).<br><br>• It is important to note that T1a, N0, M0 renal cancers are slower growing and less aggressive, with a lower risk of complications from local disease progression, such as bleeding and pain, and a lower risk of progression to metastatic disease than T1b, N0, M0 RCC (i.e. the focus of this policy proposition).<br><br>The implementation of the policy proposition is considered to have a positive impact on carers.<br><br>• Treatment options for people with with T1b, N0, M0 RCC who are medically unfit for surgery, only become available when the cancer has |

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| | progressed and the outcomes are far worse and it is very unlikely to be curative. The treatment options are also more intensive, with more side effects. The increased morbidity and mortality for these patients could necessitate the need for more assistance with care and hospital visits.<br><br>• SABR has the potential to improve an individual's health status and reduce morbidity, which may reduce the care needs of patients, allowing them to participate more in activities of daily living.<br><br>There are also likely to be benefits to people in other protected characteristic groups and other groups that face inequalities. This is because people with disabilities are likely to be members of more than one group. For example, multi comorbidities increase with age and are more common in people who live in deprived areas, are homeless or have addiction or substance misuse problems i.e. intersectionality.<br><br>The policy proposition is aimed at all adults irrespective of race and ethnicity and any protected characteristics within section 149 of the Equality Act (2010). |
| **13Q Assessment** | |
| PPVAG outcome | No consultation required |
| Were PPVAG assured of the level of stakeholder testing? | PPVAG were fully assured. |
| **Rare Disease Advisory Group** | |
| Not Applicable | |
| **Pharmaceutical** | |
| Not Applicable | |
| **National Programme of Care** | |

The proposal received the full support of the Cancer National Programme of Care.